February 27, 2001

HOUSE BILL No. 2026

DIGEST OF HB 2026 (Updated February 26, 2001 1:16 PM - DI 104)

Citations Affected: IC 16-18; IC 16-42.5.

Synopsis: Fair pricing for prescription drugs. Establishes the Rx program to provide discounted prescription drug prices to uninsured residents of Indiana. Requires the state department of health to submit an annual report to the legislative council on the enrollment and financial status of the Rx program before January 1 of each year. Requires a drug manufacturer or labeler that sells prescription drugs in Indiana through any state funded or state operated program to enter into a rebate agreement with the department that requires rebate payments to be made to the state for the Rx program each calendar quarter. Requires the state department of health to post certain information on its website. Authorizes the state department to negotiate the amount of the rebate required from a manufacturer or labeler. Requires the rebate to take effect not later than January 1, 2002. Establishes a formula for the state to use in calculating discount prices for drugs covered by the rebate agreement. Requires a retail pharmacy to sell the drugs covered by the Rx program to participants in the program at the discounted price determined by the state department beginning July 1, 2002. Establishes a procedure for resolving discrepancies in rebate amounts. Allows the state department to audit a manufacturer or labeler to determine whether the price negotiated complies with certain requirements. Provides the state with remedies for a violation. Establishes the Rx dedicated fund, consisting of: (1) revenue from manufacturers and labelers who pay rebates; and (2) appropriations or allocations to the fund.

Effective: July 1, 2001.

Kersey, Liggett

January 17, 2001, read first time and referred to Committee on Ways and Means.
February 26, 2001, amended, reported — Do Pass.

February 27, 2001

First Regular Session 112th General Assembly (2001)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2000 General Assembly.

HOUSE BILL No. 2026

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-32.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 32.5. "Average wholesale price", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-2.**

SECTION 2. IC 16-18-2-197.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 197.5. "Labeler", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-3.**

SECTION 3. IC 16-18-2-216 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 216. (a) "Manufacturer", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and IC 16-42.5,** means a person who by compounding, cultivating, harvesting, mixing, or other process produces or prepares legend drugs. The term includes a person who:

(1) prepares legend drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process; or

(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section 288(a) and 288(c) of this chapter) in the practice of their profession.

SECTION 4. IC 16-18-2-318.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 318.5. "Retail pharmacy", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-4.**

SECTION 5. IC 16-18-2-320.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 320.8 "Rx program", for purposes of IC 16-42.5, refers to the Rx program established by IC 16-42.5-2-1.**

SECTION 6. IC 16-42.5 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]:

ARTICLE 42.5. FAIR PRICING FOR PRESCRIPTION DRUGS

Chapter 1. Definitions

Sec. 1. The definitions in this chapter apply throughout this article.

Sec. 2. "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

Sec. 3. "Labeler" means a person or an entity that:

(1) receives prescription drugs from a manufacturer or wholesaler;

(2) repackages those drugs for later retail sale; and

(3) has a labeler code from the federal Food and Drug Administration under 21 CFR 207.20.

Sec. 4. "Retail pharmacy" means a retail pharmacy or another business that is licensed to dispense prescription drugs in this state and that dispenses drugs covered by a rebate agreement under the Rx program.

Chapter 2. General Provisions

Sec. 1. The Rx program is established to provide discounted prescription drug prices to uninsured residents of Indiana.

Sec. 2. (a) Residents of Indiana are eligible to participate in the Rx program if they do not have prescription drug coverage under any health insurance plan or public assistance program.

(b) The state department shall establish simplified procedures

for determining eligibility and issuing Rx program enrollment cards to eligible residents.

(c) The state department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment by eligible residents.

(d) The state department may adjust the requirements and terms of the Rx program to accommodate any new federally funded prescription drug program.

Sec. 3. The state department shall submit a report on the enrollment and financial status of the Rx program to the legislative council before January 1 of each year.

Sec. 4. The department may adopt rules under IC 4-22-2 to implement this article.

Sec. 5. The state department may do the following in implementing the Rx program:

(1) Coordinate with other governmental programs.

(2) Take actions to enhance efficiency.

(3) Reduce the cost of prescription drugs.

(4) Maximize the benefits of the Rx program and other governmental programs, including provision of the benefits of the Rx program to the beneficiaries of other state programs.

Sec. 6. The state department shall apply for any waiver of federal law, rule, or regulation necessary to implement the provisions of this article.

Chapter 3. Requirements of Drug Manufacturers and Labelers

Sec. 1. (a) A drug manufacturer or labeler that sells prescription drugs in Indiana through any state funded or state operated program shall enter into a rebate agreement with the state department for the Rx program.

(b) The rebate agreement must require the manufacturer or labeler to make rebate payments to the state each calendar quarter according to a schedule established by the state department.

Sec. 2. (a) The state department shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this chapter.

(b) When negotiating the amount of the rebate, the state department may consider the following:

(1) The rebate calculated under the federal Medicaid Rebate Program under 42 U.S.C. 1396r-8.

(2) The average wholesale price of prescription drugs.

(3) Any other information on prescription drug prices and price discounts.

(c) The rebate established under this chapter shall take effect not later than January 1, 2002. The state department shall use its best efforts to obtain a rebate amount that is at least equal to the amount of any discount, rebate, or price reduction for prescription drugs that is provided to the federal government.

Sec. 3. The names of manufacturers and labelers that do not enter into rebate agreements as required by section 1 of this chapter are public information.

Sec. 4. (a) The state department shall post on its Internet website the following information:

(1) The names and other pertinent information of the manufacturers or labelers that entered into a rebate agreement as described in section 1 of this chapter.

(2) The names and other pertinent information of the manufacturers or labelers that did not enter into a rebate agreement as described in section 1 of this chapter.

(b) The state department may publish all or part of the information described in subsection (a) in any newspaper of general circulation published in Indiana.

Chapter 4. Calculation of Discount Price

Sec. 1. The state department shall establish discounted prices at which a retail pharmacy must offer prescription drugs covered by a rebate agreement and shall promote the use of efficacious and reduced cost drugs, taking into consideration the following:

(1) Reduced prices for state and federally capped drug programs.

(2) Differential dispensing fees.

(3) Administrative overhead.

(4) Incentive payments.

Sec. 2. The state department shall use the following formulas to compute the discount prices described in section 1 of this chapter:

(1) Beginning July 1, 2001, and ending December 31, 2001:

STEP ONE: Determine the average wholesale price.

STEP TWO: Subtract six percent (6%) of the wholesale price.

STEP THREE: Add the dispensing fee provided under the state Medicaid program.

(2) After December 31, 2001:

STEP ONE: Use the prices calculated under subdivision (1).

STEP TWO: Subtract the rebate paid by the state to a retail pharmacy.

Chapter 5. Sale of Prescription Drugs at Discounted Prices

Sec. 1. (a) Beginning July 1, 2002, a retail pharmacy may not charge more than the amount computed by the state department under IC 24-42.5-4-2(2) for drugs covered by the Rx program and sold to Rx program participants.

(b) The state department shall specify the discounted price levels.

(c) In determining the discounted price levels, the state department may consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent twelve (12) month period for which the information is available.

Chapter 6. Operation of the Rx Program

Sec. 1. (a) The Indiana board of pharmacy established by IC 25-26-13-3 shall adopt rules requiring disclosure by retail pharmacies to Rx program participants of the amount of savings provided by the Rx program.

(b) The rules adopted under subsection (a) must consider and protect information that is proprietary in nature.

Sec. 2. (a) A retail pharmacy shall submit claims to the state department to enable the state department to verify the amounts charged to Rx program participants.

(b) The state department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

Sec. 3. (a) On a weekly basis, the state department shall:

(1) reimburse a retail pharmacy for discounted prices provided to Rx program participants; and

(2) pay a retail pharmacy professional fee set by the state department for each prescription dispensed by the retail pharmacy to Rx program participants.

(b) The initial professional fee shall be three dollars ($3) per prescription.

Sec. 4. The state department shall collect from each retail pharmacy utilization data necessary to calculate the amount of the rebate from a manufacturer or labeler, including statistics concerning the sale of prescription drugs to Rx program participants and other customers.

Chapter 7. Discrepancies in Rebate Amounts

Sec. 1. Discrepancies in rebate amounts must be resolved using the process established in this chapter.

Sec. 2. (a) If the manufacturer or labeler rebates less than the amount claimed by a retail pharmacy, resulting in a discrepancy

that favors the manufacturer or labeler, the state department, at the state department's expense, may hire a mutually agreed-upon independent auditor to conduct an audit to verify the accuracy of the data supplied by the manufacturer or labeler concerning the amount of the rebate.

(b) If a discrepancy still exists following an audit by the independent auditor hired by the state department, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the state department for any additional rebate amount due.

Sec. 3. (a) If the manufacturer or labeler rebates more than the amount claimed by a retail pharmacy, resulting in a discrepancy against the interest of the manufacturer or labeler, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the state department regarding the manufacturer's or labeler's rebate amount.

(b) If a discrepancy still exists following an audit by the independent auditor hired by the manufacturer or labeler, the state department shall justify the reason for the discrepancy or refund to the manufacturer any excess rebate payment made by the manufacturer or labeler.

Sec. 4. Following the procedures established in sections 2 and 3 of this chapter, either the state department or the manufacturer or labeler may request a hearing under IC 4-21.5.

Chapter 8. Rx Dedicated Fund

Sec. 1. As used in this chapter, "fund" refers to the Rx dedicated fund established by section 2 of this chapter.

Sec. 2. (a) The Rx dedicated fund is established. The fund consists of:

(1) revenue from manufacturers and labelers who pay rebates; and

(2) any appropriations or allocations to the fund.

(b) The purpose of the fund is to reimburse retail pharmacies for discounted prices provided by the pharmacies to Rx program participants. The fund shall be administered by the state department.

(c) The expenses of administering the fund shall be paid from money in the fund.

(d) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that

accrues from these investments shall be deposited in the fund.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

Chapter 9. Terms of Rebate Agreement

Sec. 1. (a) A rebate agreement entered into under IC 16-42.5-3-1 must include a verification by the manufacturer or labeler that the price negotiated in the rebate agreement complies with this article.

(b) The state department may perform an audit of any manufacturer or labeler who has entered into a rebate agreement to determine whether the manufacturer or labeler complied with subsection (a). The state department may contract with an independent individual or organization to carry out the department's duties under this subsection. A manufacturer or labeler shall provide information that the state department may reasonably require to enable it to determine whether the manufacturer or labeler is in compliance with this chapter.

(c) If the state department or its agent determines that a manufacturer or labeler has not complied with subsection (a), the state department shall require the manufacturer or labeler to do the following:

(1) Refund to the state department the difference between the price offered to the state by the rebate agreement and the lowest price offered by the manufacturer or labeler as determined by the state department's negotiating formula under IC 16-42.5-3 and IC 16-42.5-4.

(2) Promptly pay the costs of the audit.

(d) The state may hire counsel to collect any amount, including attorney's fees and the cost of collection, under subsection (c) that is not promptly paid.

(e) The state department shall deposit any money collected under subsection (c) into the Rx dedicated fund.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Ways and Means, to which was referred House Bill 2026, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 2, line 14, delete "IC 24-42.5" and insert "IC 16-42.5".

Page 4, line 8, delete "information, and the state department may" and insert "**information.**".

Page 4, delete line 9.

Page 4, line 10, after "4." insert "**(a)**".

Page 4, line 10, delete "impose prior authorization" and insert "**post on its Internet website the following information:**

(1) The names and other pertinent information of the manufacturers or labelers that entered into a rebate agreement as described in section 1 of this chapter.

(2) The names and other pertinent information of the manufacturers or labelers that did not enter into a rebate agreement as described in section 1 of this chapter.

(b) The state department may publish all or part of the information described in subsection (a) in any newspaper of general circulation published in Indiana.".

Page 4, delete lines 11 through 14.

Page 6, line 41, delete "Emergency Pricing for Prescription Drugs" and insert "**Terms of Rebate Agreement**".

Page 6, line 42, delete "Not later than July 1, 2004, the state department shall" and insert "**A rebate agreement entered into under IC 16-42.5-3-1 must include a verification by the manufacturer or labeler that the price negotiated in the rebate agreement complies with this article.**

(b) The state department may perform an audit of any manufacturer or labeler who has entered into a rebate agreement to determine whether the manufacturer or labeler complied with subsection (a). The state department may contract with an independent individual or organization to carry out the department's duties under this subsection. A manufacturer or labeler shall provide information that the state department may reasonably require to enable it to determine whether the manufacturer or labeler is in compliance with this chapter.

(c) If the state department or its agent determines that a manufacturer or labeler has not complied with subsection (a), the state department shall require the manufacturer or labeler to do the following:

(1) Refund to the state department the difference between the price offered to the state by the rebate agreement and the lowest price offered by the manufacturer or labeler as determined by the state department's negotiating formula under IC 16-42.5-3 and IC 16-42.5-4.

(2) Promptly pay the costs of the audit.

(d) The state may hire counsel to collect any amount, including attorney's fees and the cost of collection, under subsection (c) that is not promptly paid.

(e) The state department shall deposit any money collected under subsection (c) into the Rx dedicated fund.".

Delete pages 7 through 8.

and when so amended that said bill do pass.

(Reference is to HB 2026 as introduced.)

BAUER, Chair

Committee Vote: yeas 15, nays 10.